



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

November 2, 2016

Arthrex, Incorporated  
Ms. Courtney Smith  
Regulatory Affairs Manager  
1370 Creekside Boulevard  
Naples, Florida 34108

Re: K130129

Trade/Device Name: Univers Revers Shoulder Prosthesis System

Regulation Number: 21 CFR 888.3660

Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis

Regulatory Class: Class II

Product Code: PHX, KWS

Dated: April 29, 2013

Received: May 1, 2013

Dear Ms. Smith:

This letter corrects our substantially equivalent letter of May 31, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Lori A. Wiggins -S**

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**2.1 INDICATIONS FOR USE**

**Indications for Use**

**510(k) Number (if known): K130129**

**Device Name:** *Arthrex Univers Revers Shoulder Prosthesis System*

**Indications For Use:**

The *Univers Revers Shoulder Prosthesis* is indicated for use in a grossly rotator cuff deficient glenohumeral joint with severe arthropathy or a previous failed joint replacement with gross rotator cuff deficiency. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

The glenoid baseplate is CaP coated and is intended for cementless use with the addition of screws for fixation.

The uncoated cup and stem are intended for cemented use, all other components are for cementless use only.

Prescription Use  AND/OR Over-The-Counter Use \_\_\_\_\_

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Casey L. Hanley, Ph.D.  
Division of Orthopedic Devices

MAY 31 2013

## 2.2.510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

<b>Date Summary Prepared</b>	January 9, 2013
<b>Manufacturer/Distributor/Sponsor</b>	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
<b>510(k) Contact</b>	Courtney Smith Regulatory Affairs Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1720 Fax: 239/598.5508 Email: <a href="mailto:csmith@arthrex.com">csmith@arthrex.com</a>
<b>Trade Name</b>	<i>Univers Revers Shoulder Prosthesis System</i>
<b>Common Name</b>	Shoulder Prosthesis
<b>Product Code -Classification Name</b>	KWS – Prosthesis, Shoulder, semi-constrained
<b>CFR</b>	metal/polymer, cemented, CFR 888.3660
<b>Predicate Device</b>	K053274: Zimmer Anatomical Shoulder System K100142: Torneir Aequalis Revers Shoulder Prosthesis
<b>Purpose of Submission</b>	This traditional 510(k) premarket notification is submitted to obtain clearance for the <i>Univers Revers Shoulder Prosthesis System</i> .
<b>Device Description</b>	The <i>Arthrex Univers Revers Shoulder Prosthesis System</i> has an articular design that is inverted compared to traditional total shoulder prosthesis. The system is comprised of two main components; the <i>Arthrex Univers Revers Shoulder Prosthesis</i> and the <i>Universal Glenoid Shoulder Prosthesis</i> . The <i>Arthrex Univers Revers Shoulder Prosthesis</i> is a titanium humeral stem and epiphysis or humeral cup, a titanium spacer, and an UHMWPE humeral cup liner. The humeral stem and epiphysis are available uncoated or with CaP coating. The <i>Universal Glenoid Shoulder Prosthesis</i> consists of a TPS/CaP coated titanium glenoid baseplate, a cobalt

	chrome glenosphere, and titanium screws.
<i>Intended Use</i>	<p>The <i>Univers Revers Shoulder Prosthesis</i> is indicated for use in a grossly rotator cuff deficient glenohumeral joint with severe arthropathy or a previous failed joint replacement with gross rotator cuff deficiency. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.</p> <p>The glenoid baseplate is CaP coated and is intended for cementless use with the addition of screws for fixation.</p> <p>The uncoated cup and stem are intended for cemented use, all other components are for cementless use only.</p>
<i>Substantial Equivalence Summary</i>	<p>The <i>Univers Revers Shoulder Prosthesis System</i> is substantially equivalent to the predicate devices in which the basic features and intended uses are the same. Any differences between the <i>Univers Revers Shoulder Prosthesis System</i> and the predicates are considered minor and do not raise questions concerning safety and effectiveness.</p> <p>The proposed shoulder devices are substantially equivalent to the predicate devices in regards to its intended use, design, size ranges, and materials.</p> <p>The submitted mechanical testing data demonstrated that the fatigue strength of the proposed devices is substantially equivalent to the fatigue strength of the predicate devices. The mechanical data indicate that the <i>Univers Revers Shoulder Prosthesis System</i> is adequate for their intended use. Clinical data and conclusions are not needed for this device.</p> <p>Based on the indication for use, technological characteristics, and the comparison to the predicate devices, Arthrex, Inc. has determined that the <i>Univers Revers Shoulder Prosthesis System</i> is substantially equivalent to currently marketed predicate devices.</p>